Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

December 2, 2002

RE: Docket number 00D-1539: *draft Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records* issued September 5, 2002.

Dear Mr. Paul Motise:

Our company has reviewed the agency's *draft Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records*. We are providing comments for your consideration for incorporation in the final guidance.

Your guidance very thoughtfully spells out some of the considerations that should be taken when preserving information electronically over extended periods. We interpret various sections as calling for electronic record maintenance procedures, security procedures, responsibility matrices, environmental controls and monitoring, and archiving for long-term storage. These are sound information technology practices.

The guidance is not explicit as to which requirements are for archiving and which are for backups. We believe that the guidance would benefit from clear definition of **active records** as readily accessible data for day-to-day reference and use, **backup records** as periodic snapshots of the data to enhance data security, and **archive records** as longer-term storage of data to enhance retention capabilities and / or minimize active storage space requirements.

The confusion between terms is evident, as some parties have interpreted the guidance as requiring an archive copy, a backup archive copy plus the original electronic record. Three copies of a record would provide very little benefit over two copies at disparate locations. To clarify, the guidance should be explicit that regular backups are essential to the electronic record maintenance process for active records.

While we agree that a company should understand its records retention period, the life of archiving media (including limitations imposed by technology evolution), and have a policy on records retention, we do not feel that is always prudent or practical to periodically inspect media. The process of recalling the media and human factors involved with transporting, unpacking, loading, inspecting, unloading, packaging, and transporting the media are of greater potential degradation than the shelf life of the media. If, at the end of the documented life of the media the records still need to be maintained, they should be retrieved and migrated to new media with verification of the transfer.

We agree that reasonable efforts should be made to preserve electronic records in a format that can be processed, however, it may not be possible to maintain or migrate all systems over the entire retention period. For this reason, a company may be required to migrate records to an archive format that cannot be processed in the same manner as the original electronic record such as Portable Document Format (PDF) or SAS Transport Files. The worst case would be a situation where the only practical technical course of action is to print the files. We feel that the guidance should allow this once all other reasonable technical solutions are exhausted providing that all of the information is preserved and the life of the electronic record can be discerned including when it was migrated to paper.

We agree that copying procedures should have built-in copy verification mechanisms or that the tools should be validated, but the guidance should also like to allow manual verification to be used in conjunction with non-validated copying tools. For example, the Solaris operating system command cp (copy) does not perform verification, however, subsequently using the Solaris operating system command diff –b (differences switch bytes) will provide a bit by bit comparison of the copied file(s).

We feel that the time-capsule approach to maintaining electronic records will only be practical with records that have well-defined, short-term retention periods. We agree that system and user documentation should be preserved and that personnel will become unfamiliar with the system if it is not in active use. However, we feel that training may not be appropriate for an inactive system, as the trainee will not retain it. Instead, step-by-step procedures should be documented and retained both during the life of the system and once it is no longer in active use. Such procedures should include the following: system startup / shutdown; data backup / restore; data archive / retrieval; contingency planning / disaster recovery; how to review audit trails / signatures; how to inspect authentication / access control lists; how to grant / revoke access; how to create complete and accurate copies; and any other periodic maintenance requirements.

We agree with your general concerns regarding migration. However, we believe that the definition of migration is too broad. The upgrade of hardware (audio, display, and printing devices), operating systems, and applications should be considered system upgrades (or system migrations) with appropriate change control authorization, configuration control, and resulting changes recorded in the maintenance logs or appended to validation documentation concerning the system. No documentation of these types of changes should be recorded in the individual record audit trails.

The moving of files across media and file formats should be considered migrations with appropriate verifications of the ability to access metadata and discern various record attributes. When possible, it may be desirable to record the migration event in a record's audit trail, but we believe that procedural controls and documentation should suffice where the technology does not provide a practical means to append the audit trail.

We agree with your position regarding the documentation of unavoidable losses and differences when migrating records. However, we do not believe it necessary to have an

external third party certify the validity of digital (Public Key Infrastructure - PKI) signatures if the signatures are applied internal to the company. The certifications in migration documentation by internal employees concerning the validity of the original records should suffice. We understand that there would be benefits to such certifications for records migrated by parties external to the company where the party performing the migration may not be sufficiently bound to the accuracy of records.